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10/799,264

03/12/2004

Don Fishbein

52427-AA/JPW/GJG

8229

7590 10/05/2007
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EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/799,264 | Applicant(s) FISHBEIN, DON | |
| | Examiner Alicia R. Hughes | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4 sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims and Examination

Claims 30-45 are pending and the subject of this Office Action.

Applicants' arguments, filed on 27 June 2007, have been fully considered and are deemed to be persuasive regarding the previous rejection. Therefore, rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-40 and 42-45 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as "Schaffer"].

The arguments supplied in this Office's Action of 23 March 2007 are incorporated herein by reference in total.

Applicant argues that a *prima facie* case of obviousness has not been established over claims 30-45 for the following reasons: (1) the references used and the claimed invention treat are directed to different patient populations and weight loss etiologies for

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these populations are not the same and therefore, there is no demonstrable reasonable expectation of success; (2) Schaffer does not explicitly state that anabolic steroids are used systemically to treat burns, but rather, refers to medicinal literature; (3) Berger and Schaffer are not combinable, because the technical fields of the two references differ; and (4) there are unexpected results.

That the patient populations vary and therefore, the etiologies behind their weight loss are not the same is inconsequential. Simply stated, both populations have suffered weight loss and the prior art discloses that anabolic steroids, such as oxandrolone, foster an increase in appetite. If it is known in the art that oxandrolone fosters an increase in appetite, then it reasonably follows that the administration of oxandrolone would lead to weight gain.

With regard to the Schaffer reference, as a matter of law, an issued patent and the references therein are presumed to be valid. Therefore, the reference in Schaffer to the medicinal literature to support the premise that topically or systemically applied drugs accelerates the healing processes of physically, chemically, or physiologically induced tissue lesions, including burns, is presumed valid, absent any express evidence to the contrary.

In response to the Applicant's argument that the technical fields of Schaffer and Berger differ, and therefore, the subject matter does not overlap, the Office respectfully disagrees. The technical fields do overlap because both involve the administration of anabolic steroids, with Schaffer explicitly teaching their use to treat burns. Thus, the overlapping scope does motivate the combination of the references.

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Finally, that the specification teaches that even with the same calorific intake, a dramatically increased weight gain is seen in patients treated with oxandrolone is not in and of itself suggestive of unexpected results, because calorific intake alone does not contribute, exclusively to weight gain.

One of ordinary skill in the art would be motivated to combine the teachings of Berger and the teachings of Schaffer, because the patents teach overlapping subject matter, namely treatment using anabolic steroids. In light of the foregoing, and absent any evidence to the contrary, one would conclude that it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of oxandrolone, in the dosages and dosage forms disclosed in the present invention, would be an effective method for promoting weight gain after weight loss for one who experiences loss of lean body mass due to burn-induced trauma.

Claims 30 and 41 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as "Schaffer"] and in further view of U.S. Patent No. 5,434,146 [hereinafter referred to as "Labrie et al"].

The arguments, *supra*, related to the Berger and Schaffer references and in this Office's previous action of 23 March 2007 are incorporated herein by reference, in total.

Applicant argues that neither Berger nor Labie et al teach a sustained release formulation for oxandrolone. As noted prior, however, Labie et al do teach the sustained release of oxandrolone (Abstract; Col. 21, lines 17 and 61-68; and Col. 23, lines 20-24).

One of ordinary skill in the art would be motivated to combine the teachings of Berger and Schaffer with the teachings of Labrie et al., due to their overlapping subject

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matter, most notably anabolic steroids. In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of an effective amount of oxandolone in sustained release formulations would be effective for promoting weight gain after weight loss resulting from burn-induced trauma in a patient.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

25 September 2007



Alicia Hughes


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER